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FORM 1-10.1

1-75

PTO/SB/01 (8-95)

OMB 0551-0032

Approved for use through 9/30/98

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Rev. 9/93U.S. Department of Commerce
Patent and Trademark Office

Attorney Docket Number

4250-2

First Named Inventor

Robert R. Keller, M.D.

**DECLARATION FOR
UTILITY OR DESIGN
PATENT APPLICATION****COMPLETE IF KNOWN**

Application Number

Filing Date

Group Art Unit

Examiner Name

☒ Declaration OR
Submitted
with Initial Filing ☐ Declaration
Submitted after
Initial Filing

As a below named inventor, I hereby declare that:

My residence, post office address, and citizenship are as stated below next to my name.

I believe I am the original, first and sole inventor (if only one name is listed below) or an original, first and joint inventor (if plural names are listed below) of the subject matter which is claimed and for which a patent is sought on the invention entitled:

METHOD OF TREATMENT OF GLUTATHIONE DEFICIENT MAMMALS

(Title of the invention)

The specification of which

☒ is attached hereto
OR☐ was filed on (MM/DD/YYYY)

as United States Application Number or PCT International

Application Number

and was amended on (MM/DD/YYYY)

(If applicable)

I hereby state that I have reviewed and understand the contents of the above identified specification, including the claims, as amended by any amendment specifically referred to above.

I acknowledge the duty to disclose information which is material to patentability as defined in Title 37 Code of Federal Regulations, § 1.56

I hereby claim foreign priority benefits under Title 35, United States Code § 119 (a)-(d) or § 365(b) of any foreign application(s) for patent or inventor's certificate, or § 365 (a) of any PCT international application which designated at least one country other than the United States of America, listed below and have also identified below, by checking the box, any foreign application for patent or inventor's certificate, or of any PCT international application having a filing date before that of the application on which priority is claimed.

Prior Foreign Application Number(s)	Country	Foreign Filing Date (MM/DD/YYYY)	Priority Not Claimed	Certified Copy Attached?	
			<input type="checkbox"/>	YES <input type="checkbox"/>	NO <input type="checkbox"/>
			<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
			<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
			<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
			<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
			<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

☐ Additional foreign application numbers are listed on a supplemental priority sheet attached hereto.

I hereby claim the benefit under Title 35, United States Code § 119(a) of any United States provisional application(s) listed below

Application Number(s)	Filing Date (MM/DD/YYYY)	<input type="checkbox"/> Additional provisional application numbers are listed on a supplemental priority sheet attached hereto.
60/083,661	04/30/98	

Burden Hour Statement: This form is estimated to take 4 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, Patent and Trademark Office, Washington, DC 20231.

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DECLARATION				Page 2	
<p>I hereby claim the benefit under Title 35, United States Code §120 of any United States application(s), or §365(c) of any PCT international application designating the United States of America, listed below and, insofar as the subject matter of each of the claims of the application is not disclosed in the prior United States or PCT international application in the manner provided by the first paragraph of Title 35, United States Code §112, I acknowledge the duty to disclose information which is material to patentability as defined in Title 37, Code of Federal Regulations §1.56 which became available between the filing date of the prior application and the national or PCT international filing date of this application.</p>					
U.S. Parent Application Number	PCT Parent Number	Parent Filing Date (MM/DD/YYYY)	Parent Patent Number (if applicable)		
<input type="checkbox"/> Additional U.S. or PCT international application numbers are listed on a supplemental priority sheet attached hereto.					
<p>As a named inventor, I hereby appoint the following attorney(s) and/or agent(s) to prosecute this application and to transact all business in the Patent and Trademark Office connected therewith:</p>					
<input type="checkbox"/> Firm Name 				<input type="checkbox"/> Customer Number or Issue 	
<input type="checkbox"/> List attorney(s) and/or agent(s) name and registration number below:					
Name	Registration Number	Name	Registration Number		
Joseph C. Sullivan	18,720	Ronald R. Santucci	28,988		
John Kurucz	18,688	Ronald E. Brown	32,200		
Gerald Levy	24,419	John P. Gulbin	33,180		
Joseph T. Eisele	25,331	Richard J. Danyko	33,672		
Monami Roy	40,982	Clifford Ulrich	42,194		
<input type="checkbox"/> Additional attorney(s) and/or agent(s) named on a supplemental sheet attached hereto.					
<p>Please direct all correspondence to: <input type="checkbox"/> Customer Number OR <input checked="" type="checkbox"/> Fill in correspondence address below</p>					
<p>Name Ronald R. Santucci</p>					
<p>Address Kane, Dalsimer, Sullivan, Kurucz, Levy, Eisele and Richard, LLP</p>					
<p>Address 711 Third Avenue, 20th Floor</p>					
City New York,		State NY		ZIP 10017	
Country U.S.A.		Telephone 212-687-6000		Fax 212-682-3484	
<p>I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.</p>					
<p>Name of Sole or First Inventor: <input type="checkbox"/> A petition has been filed for this unsigned inventor</p>					
Given Name	Robert	Middle Initial	R	Family Name	Keller
					Suffix e.g. Jr. M.D.
Inventor's Signature				Date	4/29/97
Residence: City Weston		State FL		Country U.S.A.	
Post Office Address 501 Ranch Road					
Post Office Address 					
City Weston	State FL	Zip 33326	Country U.S.A.		Applicant Authority
<input checked="" type="checkbox"/> Additional inventors are being named on supplemental sheet(s) attached hereto					

(Declaration for Utility or Design Patent Application (PTO/SB/01) [1-10.1]—page 2 of 3)

DECLARATION						ADDITIONAL INVENTOR(S) Supplemental Sheet	
Name of Additional Joint Inventor, if any:						<input type="checkbox"/> A petition has been filed for this unsigned inventor	
Given Name	David	Middle Initial	W	Family Name	Kirshenbaum	Suffix e.g., Jr.	
Inventor's Signature					Date	4/29/99	
Residence: City	Weston	State	FL	Country	U.S.A.		Citizenship
Post Office Address		3272 Huntington					
Post Office Address							
City	Weston	State	FL	Zip	33332	Country	U.S.A.
Name of Additional Joint Inventor, if any:						<input type="checkbox"/> A petition has been filed for this unsigned inventor	
Given Name		Middle Initial		Family Name		Suffix e.g., Jr.	
Inventor's Signature					Date		
Residence: City		State		Country			Citizenship
Post Office Address							
Post Office Address							
City		State		Zip		Country	
Name of Additional Joint Inventor, if any:						<input type="checkbox"/> A petition has been filed for this unsigned inventor	
Given Name		Middle Initial		Family Name		Suffix e.g., Jr.	
Inventor's Signature					Date		
Residence: City		State		Country			Citizenship
Post Office Address							
Post Office Address							
City		State		Zip		Country	
Name of Additional Joint Inventor, if any:						<input type="checkbox"/> A petition has been filed for this unsigned inventor	
Given Name		Middle Initial		Family Name		Suffix e.g., Jr.	
Inventor's Signature					Date		
Residence: City		State		Country			Citizenship
Post Office Address							
Post Office Address							
City		State		Zip		Country	

☐ Additional inventors are being named on supplemental sheet(s) attached hereto

VERIFIED STATEMENT (DECLARATION) CLAIMING SMALL ENTITY STATUS (37 CFR 1.9(f) AND 1.27 (c)) - SMALL BUSINESS CONCERN			Docket No. 4250-2
Serial No.	Filing Date herewith	Patent No.	Issue Date
Applicant/ Robert H. Keller, M.D. and David W. Kirshenbaum Patentee:			
Invention: Method of Treatment of Glutathione Deficient Mammals			
<p>I hereby declare that I am:</p> <p><input checked="" type="checkbox"/> the owner of the small business concern identified below:</p> <p><input type="checkbox"/> an official of the small business concern empowered to act on behalf of the concern identified below:</p> <p>NAME OF CONCERN: <u>VIT-IMMUNE, L.C.</u></p> <p>ADDRESS OF CONCERN: <u>5821 Hollywood Boulevard, Hollywood, Florida 33021</u></p> <p>I hereby declare that the above-identified small business concern qualifies as a small business concern as defined in 13 CFR 121.3-18, and reproduced in 37 CFR 1.9(d), for purposes of paying reduced fees under Section 41(a) and (b) of Title 35, United States Code, in that the number of employees of the concern, including those of its affiliates, does not exceed 500 persons. For purposes of this statement, (1) the number of employees of the business concern is the average over the previous fiscal year of the concern of the persons employed on a full-time, part-time or temporary basis during each of the pay periods of the fiscal year, and (2) concerns are affiliates of each other when either, directly or indirectly, one concern controls or has the power to control the other, or a third party or parties controls or has the power to control both.</p> <p>I hereby declare that rights under contract or law have been conveyed to and remain with the small business concern identified above with regard to the above identified invention described in:</p> <p><input checked="" type="checkbox"/> the specification filed herewith with title as listed above.</p> <p><input type="checkbox"/> the application identified above.</p> <p><input type="checkbox"/> the patent identified above.</p> <p>If the rights held by the above-identified small business concern are not exclusive, each individual, concern or organization having rights to the invention is listed on the next page and no rights to the invention are held by any person, other than the inventor, who could not qualify as an independent inventor under 37 CFR 1.9(c) or by any concern which would not qualify as a small business concern under 37 CFR 1.9(d) or a nonprofit organization under 37 CFR 1.9(e).</p>			

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Each person, concern or organization to which I have assigned, granted, conveyed, or licensed or am under an obligation under contract or law to assign, grant, convey, or license any rights in the invention is listed below:

- ☒ no such person, concern or organization exists.
☐ each such person, concern or organization is listed below.

FULL NAME
ADDRESS

☐ Individual ☐ Small Business Concern ☐ Nonprofit Organization

FULL NAME
ADDRESS

☐ Individual ☐ Small Business Concern ☐ Nonprofit Organization

FULL NAME
ADDRESS

☐ Individual ☐ Small Business Concern ☐ Nonprofit Organization

FULL NAME
ADDRESS

☐ Individual ☐ Small Business Concern ☐ Nonprofit Organization

Separate verified statements are required from each named person, concern or organization having rights to the invention averring to their status as small entities. (37 CFR 1.27)

I acknowledge the duty to file, in this application or patent, notification of any change in status resulting in loss of entitlement to small entity status prior to paying, or at the time of paying, the earliest of the issue fee or any maintenance fee due after the date on which status as a small entity is no longer appropriate. (37 CFR 1.28(b))

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application, any patent issuing thereon, or any patent to which this verified statement is directed.

NAME OF PERSON SIGNING:

RH KELLER MD

TITLE OF PERSON SIGNING

OTHER THAN OWNER:

ADDRESS OF PERSON SIGNING:

5821 Hollywood Boulevard
Hollywood, Florida 33021

SIGNATURE:

RH Keller MD

DATE:

4/29/99